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| **Voluntary Medical Male Circumcision (VMMC) Continuous Quality Improvement (CQI)**    **Level 1 – Safety of Procedure – PREPEX PROCEDURE**  **Site Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reviewer’s Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | |
| **Male Circumcision Procedure** | | | | | | | |
| This section assesses standards to ensure:   * The procedure room is suitable for male circumcision by ShangRing * Materials and supplies for male circumcision procedure are in stock * The providers prepare the client for male circumcision procedure * The providers apply topical anesthetic and perform device placement correctly * The provider gives client appropriate post-placement care instructions * Client records are updated and completed prior to discharge * Device is removed in alignment with manufacturer instructions for use * Post-removal instructions are provided on wound care, potential complications and danger signs, return visits, and abstinence/resumption of sexual activity, and post-removal adverse events are recorded   All assessments should be determined through direct observation. Select “yes” if the item being assessed is present/adequate; select “no” if the item being assessed is not adequate; select N/A only if the item being assessed is not applicable. If an item is not available for observation but otherwise necessary, select “no”. | | | | | | | |
| **Placement** | | | | | | | |
| *Observe the following:* | | | **Y** | **N** | **N/A** | **Notes** | |
| L1-PP-1. **Male Circumcision Procedure** – Skilled surgical backup is available within 6 hours of site. | | |  |  |  |  | |
| L1-PP-2. **Male Circumcision Procedure** – A written referral/transport plan in place for surgical backup. | | |  |  |  |  | |
| *Observe the procedure room for the following:* | | |  | | | | |
| L1-PP-3. **Male Circumcision Procedure** –Availability of operating/strong lights. | | |  |  |  |  | |
| L1-PP-4. **Male Circumcision Procedure** – Restriction of access (signage is sufficient). | | |  |  |  |  | |
| L1-PP-5. **Male Circumcision Procedure** – Privacy is available to each patient (doors with handles & locks separating procedure room from rest of clinic; beds enclosed by curtains; at least 1m between patient beds – if services are provided in tents, beds should at least be enclosed by curtains and 1m apart). | | |  |  |  |  | |
| L1-PP-6. **Male Circumcision Procedure** – The procedure rooms have adequate temperature control, ventilation, and space. | | |  |  |  |  | |
| L1-PP-7. **Male Circumcision Procedure** – There is a designated space for surgical scrub with clean running water, soap, and access to sterile towel and PPE. | | |  |  |  |  | |
| L1-PP-8. **Male Circumcision Procedure** – Use of PPE by all personnel, at all times (at a minimum: masks, caps, shoe covers). | | |  |  |  |  | |
| *Physically verify that:* | | |  | | | | |
| L1-PP-9. **Male Circumcision Procedure** – MC instrument set contains necessary instruments to perform the PrePex procedure:   * PrePex devices in all prequalified sizes (A-E), with all components (placement ring, elastic ring with intact verification thread, inner ring) “o” drape (80 cm x 80 cm, with ~ 5 cm hole) * PrePex sizing plate (for placement) * Examination gloves (for placement and removal) * Povidone iodine (50 mL 7.5–10% aqueous-based solution), for placement and removal a * Gallipot * Skin marker (for placement) * Gauze (for placement) * 5% anesthetic cream (for placement) * Nurse utility scissors (for placement) * Sterile Harvey wire scissors (for removal) * Sterile forceps (for removal) * Sterile spatula (for removal) * Sterile scalpel (for removal) * 5 wound dressings (for removal)   a It is important to have available alternative solutions for skin disinfection, such as chlorhexidine gluconate (2% ‐ 4%), for patients allergic to povidone iodine. | | |  |  |  |  | |
| *Please obtain permission from the clinical staff to observe procedures. Then obtain verbal consent from the client (and from the parent/guardian if the client is a minor) to observe.*  *Observe in the care of two clients whether the providers do the following:* | | | | | | | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-PP-10. **Male Circumcision Procedure** – Prepare the necessary equipment. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-PP-11. **Male Circumcision Procedure** – Verify client’s name and age. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-12. **Male Circumcision Procedure** – Check for consent. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-13. **Male Circumcision Procedure** – Ask client whether they are allergic to iodine antiseptic prior to applying povidone‐iodine (7.5% ‐ 10%), and if allergic, use chlorhexidine gluconate (2% ‐ 4%) instead. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-14. **Male Circumcision Procedure** – Check for phimosis and physiological adhesions. *If either is present, MC with PrePex is contraindicated and another method should be used.* | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-15. **Male Circumcision Procedure –** Clean genitalia and surrounding area (from umbilicus to mid-thigh) with **three applications** of povidone-iodine (7.5% - 10%) or chlorhexidine gluconate (2% - 4%), and allow it to dry for at least two minutes. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-16. **Male Circumcision Procedure –** Measure penis with fresh sizing plate, taking care not to pull on the penis. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-17. **Male Circumcision Procedure –** Measure penis with fresh sizing plate, taking care not to pull on the penis. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-18. **Male Circumcision Procedure** – Mark penis for ring placement. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-19. **Male Circumcision Procedure** – Apply anesthetic cream. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-20. **Male Circumcision Procedure** – Place elastic ring on placement ring. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-PP-21. **Male Circumcision Procedure** – Position the placement ring (with mounted elastic ring) down past the line of circumcision on the penis shaft with the elastic ring distal to the body. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-22. **Male Circumcision Procedure** – Holding the foreskin on dorsal and ventral sides, stretch the foreskin up for inner ring placement. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-23. **Male Circumcision Procedure** – Place inner ring over and past the glans so that it is positioned on the sulcus, assuring that one of the flat sides of the inner ring is in the area of the frenulum and the other flat side is on the opposite side of the frenulum. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-24. **Male Circumcision Procedure** – Move the placement ring and elastic ring up toward the glans so that the elastic ring surrounds with the inner ring groove and that the elastic ring and inner ring are aligned. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-25. **Male Circumcision Procedure** – Release elastic ring from placement ring one leg at a time, so that the elastic ring drops into the inner ring groove. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-26. **Male Circumcision Procedure** – Verify placement, including alignment of rings and markings all the way around the penis. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-27. **Male Circumcision Procedure** – If alignment is incorrect, use the verification thread to pull the elastic ring off the penis, re-mount and place again – repeat as needed until alignment is correct. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-28. **Male Circumcision Procedure** – Remove verification thread. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-29. **Male Circumcision Procedure** – Discard placement ring. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-30. **Male Circumcision Procedure** – Assess and document any adverse events, including pain. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-PP-31. **Male Circumcision Procedure** – Complete the device placement notes on client record. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| *Observe whether the provider does the following:* |  | | | | | | |
| L1-PP-32. **Male Circumcision Procedure** – Explains the need to avoid intercourse and masturbation while wearing the device. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-33. **Male Circumcision Procedure** – Discusses risk reduction methods if abstinence is absolutely not possible: masturbation poses less risk than sexual intercourse; use a condom if intercourse is not avoidable, but note any type of sexual activity may displace the device, which could result in complications or surgery. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-34. **Male Circumcision Procedure** – Instructs client to wear clean underwear that fits comfortably and allows penis to stay in position while healing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-35. **Male Circumcision Procedure** – Instructs client to bathe normally and keep the inner foreskin clean, while taking care not to dislodge or move the device. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-36. **Male Circumcision Procedure** – Reminds client to return for device removal after 7 days. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-37. **Male Circumcision Procedure** – Instructs client not to let anyone but a qualified provider remove the device, as this could result in complications and surgery. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-38. **Male Circumcision Procedure** – Instructs client not to apply any home remedies or traditional medicines, such as herbal remedies, ash, or animal dung, as these can increase chances of tetanus, which can be fatal. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-39. **Male Circumcision Procedure** – Explains normal symptoms while wearing device included foreskin becoming darker and dry, odor, and pain that is manageable with analgesic tablets. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-PP-40. **Male Circumcision Procedure** – Explains how to recognize and return in case of any danger signs or signs of complications (displaced device, difficulty in passing urine, uncontrollable pain, swelling, excessive bleeding, oozing of pus). | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-41. **Male Circumcision Procedure** – Gives information on how to manage penile erections while wearing the device: spontaneous erections may feel uncomfortable, but ordinarily are not a cause for concern, and urinating at the first urge may reduce their duration/severity; contact VMMC site if device appears to have moved as a result of erection. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-42. **Male Circumcision Procedure** – Makes sure the client knows where to go if complication arise and have a contact phone number. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-43. **Male Circumcision Procedure** – Gives next appointment date. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-44. **Male Circumcision Procedure** – If age appropriate and/or sexually active client, provides condoms. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-45. **Male Circumcision Procedure** – Reinforce HIV prevention messages. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| *Observe whether a staff member or healthcare provider:* |  | | | | | | |
| L1-PP-46. **Male Circumcision Procedure** – Fills in the removal date on the client appointment card. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-47. **Male Circumcision Procedure** – Fills in emergency contact number on the client appointment card. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-48. **Male Circumcision Procedure** – Completes VMMC Client Record. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-PP-49. **Male Circumcision Procedure** – Records any post-placement complications or adverse events on the VMMC Client Record and Adverse Event Form. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| **Removal** | | | | | | | |
| *Observe whether the providers do the following:* |  | | | | | | |
| L1-PP-50. **Male Circumcision Procedure –** Assess and document any AEs that have occurred while device has been in situ | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-51. **Male Circumcision Procedure –** Apply antiseptic solution between the foreskin and glans. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-52. **Male Circumcision Procedure –** Prepare foreskin for removal by pulling it gently upwards along its whole circumference to separate it from glans. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-53. **Male Circumcision Procedure –** Cut foreskin diagonally until inner ring is reached, then cut foreskin along inner ring, as close to the ring as possible. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-54. **Male Circumcision Procedure –** Using surgical blade, cut elastic ring on flat part of the inner ring with the sharp side facing necrotic tissue. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-55. **Male Circumcision Procedure –** Clean the glans and shaft thoroughly with povidone iodine or chlorhexidine gluconate. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-56. **Male Circumcision Procedure –** Use spatula to remove inner ring. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-57. **Male Circumcision Procedure –** Examine wound for any bleeding. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-58. **Male Circumcision Procedure –** Apply dressing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-PP-59. **Male Circumcision Procedure –** Document any AEs during removal, including pain. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-60. **Male Circumcision Procedure –** Complete device removal notes on client record. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| *Observe whether the providers do the following:* |  | | | | | | |
| L1-PP-61. **Male Circumcision Procedure –** Explain the need to avoid intercourse and masturbation for 6 weeks after device removal. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-62. **Male Circumcision Procedure –** Discuss risk reduction methods if abstinence is absolutely not possible: masturbation poses less risk than sexual intercourse; use a condom if intercourse is not avoidable, but note any type of sexual activity may result in complications or prolong wound healing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-63. **Male Circumcision Procedure –** Instruct client to keep the dressing dry. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-64. **Male Circumcision Procedure –** Remind client to return for follow-up after 2 days or any time he has a concern. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-65. **Male Circumcision Procedure –** Instruct client to wash gently using soap and clean water every day, and dry carefully. He should not rub while washing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-66. **Male Circumcision Procedure –** Instruct client to handle with penis care for 2 weeks, or until the skin has grown back over the wound. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-67. **Male Circumcision Procedure –** Instruct client not to apply any home remedies or traditional medicines, such as herbal remedies, ash, or animal dung, as these can increase chances of tetanus, which can be fatal. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-PP-68. **Male Circumcision Procedure –** Explain normal symptoms post-device removal include a large band of necrotic tissue that will fall off naturally within 2-3 weeks and should not be removed by client and white tissue (slough); the remaining foreskin will dry and fall off within 1-2 weeks. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-69. **Male Circumcision Procedure –** Complete the follow-up notes section of the VMMC Client Record. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-70. **Male Circumcision Procedure –** Record any complications or adverse events on the MC Client Record and Adverse Event Recording Form. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-71. **Male Circumcision Procedure –** If age appropriate and/or sexually active client, provide condoms. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-PP-72. **Male Circumcision Procedure –** Review and reinforce HIV prevention messages. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| **Additional Comments/Notes:** | | | | | | | |